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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,137	05/15/2006	Jussi Nurmi	TUR-181	3667

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EXAMINER	
MUMMERT, STEPHANIE KANE	
ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,137	NURMI ET AL.	
	Examiner	Art Unit	
	STEPHANIE K. MUMMERT	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,19 and 21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19 and 21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on July 2, 2010 is acknowledged and has been entered. Claim 18 has been amended. Claims 1-17 and 20 have been canceled. Claims 18-19 and 21-30 are pending.

Claims 18-19 and 21-30 are discussed in this Office action.

All of the amendments and arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This action is made FINAL as necessitated by Amendment.

New Grounds of Rejection as necessitated by Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-19 and 21-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Daridon et al. (US PgPub 2004/0229349; 102(e) date, April 1, 2002). Daridon teaches a filtration and sorting apparatus useful for detection of cellular materials (Abstract).

With regard to claim 18, Daridon teaches an assay for quantitative and/or qualitative analysis of the presence of a specific analyte or specific analytes in a biological sample, which analytes, if present, are contained in biological particles of said sample, said assay comprising forcing said sample in a first direction through a filter that retains said biological particles (Fig 17 and 18, p. 30, paragraph 443-449, 622 is the filter and is designed to pass fluid readily, but will retain particles and may be size selective, see [446] and [449], where particle 620 is retained), removing biological particles from said filter by a flush flow in a second direction opposite said first direction, and analyzing biological particles contained in said flush flow (p. 30, [449] where particle is displaced by fluid flowing in reverse across filter channel and repositioned to analysis site 632), and analyzing biological particles contained in said flush flow by means of a nucleic acid amplification assay (paragraph 246, 288, 307, where the retained particle or cell can be analyzed by PCR amplification), wherein said flush flow is analysed for the analyte or analytes without any further purification (p. 30, [449] where the repositioned particle is moved to an analysis site without further purification).

With regard to claim 19, Daridon teaches an embodiment of claim 1, further comprising performing an initial filtration which does not retain the biological particles containing the analyte or analytes but retains particles that might interfere with the analysis of the analyte or analytes, said initial filtration being performed prior to forcing said sample in a first direction

through a filter which retains said biological particles (Embodiment 4, [538] where the system flushes fluid through the chamber to prevent clogging of the filter).

With regard to claim 21, Daridon teaches an embodiment of claim 1, wherein retention of the biological particles containing the analyte or analytes in the filter is dependent on the size of the particles (p. 30, [446] where "in some embodiments, the diameter of filter channel 616 allows size-selective retention of a single particle").

With regard to claim 22, Daridon teaches an embodiment of claim 1 wherein retention of the biological particles containing the analyte or analytes in the filter is essentially dependent on the chemical properties of the particle (p. 14 [253] where the particle is retained based on a chemical interaction).

With regard to claim 23, Daridon teaches an embodiment of claim 18, wherein the biological particles containing the analyte or analytes are selected from the group consisting of prokaryotic or eukaryotic cells or spores or components thereof, viruses or viral particles, complexes comprising protein and/or nucleic acid, and any combination thereof (p. 7-8, [149-164], where the particles or analytes include biological cells including eukaryotic and prokaryotic cells and viruses).

With regard to claim 24, Daridon teaches an embodiment of claim 6, wherein the biological particles containing the analyte or analytes are selected from the group consisting of bacteria, bacterial cell, plant pollen, mitochondria, chloroplast, cell nuclei, virus, phage, chromosome and ribosome (p. 7-8, [149-164], where the particles or analytes include biological cells including eukaryotic and prokaryotic cells and viruses).

With regard to claim 25, Daridon teaches an embodiment of claim 1, wherein the means of analysing the analyte or analytes is selected from the group consisting of polymerase chain reaction (PCR), reverse transcriptase polymerase chain reaction (RT-PCR), ligase chain reaction (LCR), proximity ligation assay, nucleic acid sequence based amplification (NASBA), strand displacement amplification (SDA) and any combination thereof (p. 14, [246], where the types of analysis include PCR).

With regard to claim 26, Davidon teaches an embodiment of claim 1, wherein said flush flow comprises a liquid or gas not contained in said sample (p. 9, [177] where positioning or facilitation mechanisms can include external liquid or gas pressure).

With regard to claim 27, Daridon teaches an embodiment of claim 1 wherein the analyte or analytes are selected from the group consisting of a living and/or dead cell or virus; a peptide, a protein or complex thereof; a nucleic acid; and any combination thereof (p. 7-8, [149-164], where the particles or analytes include biological cells including eukaryotic and prokaryotic cells and viruses).

With regard to claim 28, Daridon teaches an embodiment of claim 10, wherein the analyte or analytes comprises living and/or dead cells and/or viruses selected from the group consisting of a mold, a yeast, a eukaryotic cell or organism, a pathogenic virus and a cancer cell (p. 7-8, [149-164], where the particles or analytes include biological cells including eukaryotic and prokaryotic cells and viruses).

With regard to claim 29, Daridon teaches an embodiment of claim 10, wherein the analyte or analytes comprises nucleic acids selected from the group consisting of DNA, RNA and any derivative thereof (p. 12-13, [223] where the nucleic acids can include DNA or RNA).

With regard to claim 30, Daridon teaches an embodiment of claim 10, wherein the analyte or analytes comprises peptides and/or proteins or complexes thereof selected from the group consisting of a hormone, a growth factor, an enzyme or parts thereof and/or complexes thereof; and any combination thereof (p. 14, [248] where the characteristic detected in the analyte includes nucleic acids, proteins, enzymes and a variety of additional factors).

Response to Arguments

Applicant's arguments filed July 10, 2010 have been fully considered but they are not persuasive.

Applicant traverses the rejection of claims as being anticipated by Daridon. Applicant argues that Daridon "fails to disclose or suggest the step of analyzing biological particles contained in the flush flow using a nucleic acid amplification assay without purification" (p. 7 of remarks). Applicant goes on to note the locations within Daridon where amplification or PCR are mentioned and argue that "none of these references…disclose or suggest nucleic acid amplification analysis of an analyte without any purification" (p. 7-8 of remarks). Applicant goes through each citation and appears to argue that the lack of specific mention of a lack of purification as an indication of a teaching away from the instant invention.

Then, Applicant points to paragraph 449, as cited and argues "this paragraph merely discloses directing the flush flow to a separate analysis site" and that "no mention is made, one way or the other, regarding purification of the flush flow" (p. 9 of remarks). Applicant concludes that one of skill would not interpret the paragraph as "disclosing or suggesting nucleic

acid amplification analysis should be performed without purification of the flush component… given the total absence of such disclosure in the paragraphs" (p. 9 of remarks).

These arguments have been considered, but are not persuasive. Applicant's argument that the lack of active teaching regarding a need for analysis without purification somehow suggests that purification must occur during the movement of the sample is wholly unpersuasive. The mere assumption that purification must occur simply because it is not mentioned that it should be avoided has no basis in the reference. Applicant's speculation of an event is not a basis for overcoming the rejection. To the contrary, one of ordinary skill would assume that if purification was intended, it would have been mentioned. Further, as noted in the rejectionm the Daridon reference indicates direct transfer of the sample from one site to another, which does not in any way suggest that purification steps are intended and not recited. To assume that it does, based on movement of the sample is not persuasive. Therefore, Applicant's arguments are not persuasive and the rejection is maintained.

Conclusion

All claims stand rejected, no claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHANIE K. MUMMERT whose telephone number is (571)272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephanie K. Mummert/
Primary Examiner, Art Unit 1637

SKM